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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,507	03/26/2001	Darryl DesMarteau	CXU-329	8867

7590

02/17/2004

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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,507

Applicant(s)

DESMARTEAU ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-32 and 34-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31, 32, 34-44, 46 and 47 is/are allowed.
- 6) ☒ Claim(s) 20-30 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Pursuant to the directives of the response filed 11/26/03, claims 20, 25, 32, 35, 37-39, 41-44, 46, 47 have been amended, and claim 33 cancelled. Claims 20-32, 34-47 remain pending.

Applicants' arguments filed 11/26/03 have been considered and found persuasive in part. The rejection of claim 31 over Carr, S. (*Biomedical Mass Spectrometry* 8(2), 51-61, 1981) is withdrawn. Claims 31, 32, 34-44, 46-47 are allowable.

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The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As indicated previously, it appears that descriptive support is lacking for claims 30 and 45. In arguing for descriptive support, the response states the following:

"In the specification, at the first paragraph of page 5, the compounds of the disclosed invention are discussed in regard to the lipophilic characteristics of the compounds due to the presence of the carbofluorine group on the compounds. In particular, this paragraph discusses that proteins may be reacted with the disclosed compounds

containing carbofluorine groups to produce more lipophilic structures as compared to their fully hydrogen-saturated counterparts. In addition, in the first paragraph of page 6, the specification discloses that structures embodied by the disclosed invention may be incorporated into animal or human proteins having biological application (page 6, lines 9-11). In the specification at page 14, lines 14-18, and at page 18, lines 15-19, can be found teachings concerning the reactivity of the disclosed compounds, and in particular, the finding that the reactivity of the disclosed amino acids is reversed relative to the known N-alkyl amino acids. That is, reaction occurs only at the carboxyl group of the amino acid, under the routine conditions used for N-protected amino acids in peptide synthesis (page 18, lines 15-19)"

First, the passage cited on page 5 makes no reference to the claimed compounds. The implication of the passage is that compounds which are different from those being claimed can be reacted with proteins to increase the lipophilicity of proteins. Next, the cited passage on page 6 (lines 9-11) does state that compounds of the formula on page 5 can be incorporated into proteins. However, this passage provides no indication of the kind of structures that might result from such "incorporation". Next, the response points to page 14 of the specification, where it is stated that the reactivity of amino acids 4a-4c is "reversed". It is not made clear what exactly is meant by "reversed", but certainly the organic chemist of ordinary skill would recognize that the nucleophilicity of an amino group bearing a trifluoroethyl group (and a hydrogen) is going to be far lower than that of an amino group bearing just two hydrogens (and no trifluoroethyl group). The passage at page 18, lines 15-19 makes that point that the reactivity of an N-trifluoroethyl group is sufficiently low that protection of the amino group is not required. This also does not

provide descriptive support for the claimed structure. Next, the response makes the following assertion:

"Specifically, the disclosure teaches that amino acids or peptides of the invention can be combined with proteins to **form novel esters**, and in forming the novel esters, the combination of the two components will occur at the carboxyl end of the amino acid or the peptide"

However, no page or line number is cited for this reference to "novel esters", and none is evident. If one were to prepare an active ester of an amino acid such as that recited in claim 20, and if one were to then combine that with a protein (e.g., albumin) in aqueous solution, the result would be that virtually all reaction would take place at the *epsilon*- amino groups of the lysines. If any sulfhydryl groups were present (not in disulfide linkage), these would react also (to form thioesters). The rejected claims, however, require R2 (of claim 25) to be a protein, and R3 of claim 32 to be a protein. Presumably, the point of bonding occurs at a serine or threonine (or perhaps a tyrosine). However, there is no indication in the specification of such a structure, nor is a route of synthesis of such a structure even implied. As indicated above, reaction between an active ester (of an amino acid or peptide) will occur at lysine amino groups, and cysteine sulfhydryl groups. Reaction at serine will not occur to any appreciable extent. In principle, one could take a protein, protect all of the amino and sulfhydryl reactive groups, then acylate the hydroxyl groups, then deprotect the amino and sulfhydryl groups. But such acylation of hydroxy groups on proteins will not be a facile process in aqueous or hydroxylic media. As for

aprotic media, the volume of literature on reaction of proteins in such media is quite limited, and one cannot reasonably argue that it would have been obvious to the chemist of ordinary skill to protect the reactive groups of a protein, to then carry out acylation reactions in aprotic media, and then to deprotect the amino and sulfhydryl groups.

In addition to the foregoing, the rejected claims require that the term "protein" is somehow subgeneric to one of the terms alkyls, aromatic groups, amines, thioalkyl groups, or heterocyclic groups. This is not consistent with art-recognized meanings of these terms

It is maintained that descriptive support is lacking for each of claims 30 and 45.

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Claims 20-30 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As indicated previously, claim 20 is drawn to a composition. A composition, however, must have two components. Claim 20 thus mandates the presence of a second component, but at the same time is silent as to what this second component is or should be. In the response filed 11/26/03, it is argued that various other compounds may be present. Such an explanation is a useful first step in a dialog, but the claims remain indefinite as to the second component. The response also appears to be asserting that the term "composition of matter" is somehow subgeneric to the term "composition". In organic chemistry, one

is generally dealing with compounds that have fully defined structures. Certainly, when an organic chemist provides the structure of a simple molecule on a sheet of paper, there is no ambiguity as to whether one compound is being referred to, or multiple compounds.

Perhaps in a field such as geology, the analysis is different. But in organic chemistry, a clear distinction is drawn between a single, pure compound, and multiple compounds.

In organic chemistry, when a structure of a single compound is being referred to, such a compound is not a composition. By contrast, if an organic chemist were provided with

a vial containing a powder, and the chemist were informed only that the elemental composition were, e.g., $C_{30}H_{56}N_5O_7$, it would not be appropriate to assume that the specimen represented a single, pure compound. But if a chemist were to draw the

structure of a compound such as glycine on a piece of paper, and were to assert that the structure represents a "composition", rather than a compound, such an assertion would be inconsistent with the meaning of the terms "composition" and "compound" as these terms are used by organic chemists. The analysis of the situation might be different for the

term "composition of matter", but since the term "composition of matter" does not appear in the claims, no such analysis will be attempted. Given that the field of relevance is

organic chemistry (and not physics or geology or petroleum chemistry or inorganic chemistry) the term "composition", without further qualification, refers to a mixture of at least two compounds. The claims remain indefinite as to the nature of the second

component.

Next, the response argues that the claimed subject matter meets the requirements of 35 USC §101. The relevance of this is unclear, however, since the examiner has never argued lack of patentable utility.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

D. Lukton 2/11/04

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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